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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,693	02/01/2002	Chris Polman	A088 US	3229
26161	7590	05/03/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER
			1614	
DATE MAILED: 05/03/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,693

Applicant(s)

POLMAN, CHRIS

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Applicant's Request for Continued Prosecution filed April 19, 2004 is acknowledged and accepted. New claims 15-26 are presented. Accordingly, claims 2-26 are now under consideration.

An Information Disclosure Statement filed April 19, 2004 is further acknowledged and has been reviewed.

Claims 15, 17, 19, 21, 23 and 25 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. 6-(Trifluoromethoxy)-2-benzothiazolamine is riluzole.

Claims 16, 18, 20, 22, 24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 16, 18, 20, 22, 24 and 26 recite the limitation "salt". There is insufficient antecedent basis for this limitation in the independent claims.

Claims 1-14 were rejected in the last Office Action under 35 U.S.C. 103 as being unpatentable over Arnold et al., WO 98/41882.

Applicant's arguments in response to this rejection have been considered but are not persuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arnold et al., WO 98/41882.

Arnold teaches the administration of a pharmaceutical composition comprising riluzole to treat neurodegenerative diseases for which N-acetylaspartate decline has been observed, as in multiple sclerosis. See the abstract where "treatment with the drug" is set forth as the therapeutic goal. See page 3, lines 31-33, as well as claim 3, page 15, where multiple sclerosis is clearly encompassed within the neurologic diseases contemplated by Arnold. The claims differ with respect to inhibiting the development of spinal cord atrophy associated with multiple sclerosis; the co-administration of an additional agent; primary- or secondary progressive multiple sclerosis and relapsing multiple sclerosis. However, the administration of multiple therapeutic agents is conventional when treating multiple sclerosis. The disease process is often characterized by development of spinal cord atrophy. Its inhibition is a primary therapeutic goal. It would have been reasonable to expect where the effect of riluzole is clearly on the function of the nerve cells in a patient suffering from multiple sclerosis, all types – primary-progressive, secondary-progressive and relapsing – would have been encompassed in Arnold's teaching. Formulations involving a pharmaceutically acceptable salt are conventional where issues of solubility or stability may arise.

No claim is allowed.

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Any inquiry concerning this communication should be directed to Phyllis G.

Spivack at telephone number 571-272-0585.

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

April 29, 2004

PHYLLIS SPIVACK
PRIMARY EXAMINER